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REMARKS

Claims 1- 19 and 23-26 are pending in this application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1-5, 12-17, and 23-26 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,453,097 to Paradis.

Claim 1 recites "[a] valve apparatus for medical applications, comprising a first flexible disk extending across a first lumen through which a flow of materials is to be controlled, the first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit extending through the first flexible disk, *the first moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the first flexible disk, the first moveable elements are maintained in a closed position in which no flow is permitted past the first flexible disk* and, when a pressure at least as great as the threshold value is applied to the first flexible disk, the first moveable elements are moved to an open position separated from one another along the at least one first slit permitting flow through the first lumen."

In contrast, Paradis discloses a slotted-disk check valve 10 for an IV bag which always permits flow in a downward direction and which always prevents flow in an upward direction. Specifically, the disk 10d "seals or 'checks' the channel 11 when there is upward flow in the channel 22, and opens when there is downward flow in the channel 11. *Paradis*, col. 5, line 64 to col. 6, line 1. Thus, the disk 10d prevents flow upward into the channel 11 regardless of the pressure of the back flow and permits flow downward from the IV bag through the channel 11 regardless of the downward pressure. That is, no threshold pressure is described for the valve 10d and it appears likely that fluid is permitted to drip from the IV bag until the bag is empty as in standard IV bags. The advance claimed in Paradis is the simplicity of the check valve and its effectiveness in preventing back flow. No function of the valve is described in regard to halting downward flow and no purpose would be served by a valve exhibiting the claimed characteristics.

Specifically, the disk of Paradis does not include first movable members "*biased so that, when a pressure less than a predetermined threshold value is applied to the first flexible disk, the first moveable elements are maintained in a closed position in which no flow is permitted past the first flexible disk,*" as recited in claim 1 and it is respectfully submitted that claim 1 is allowable.

Because claims 2-5 and 12-14 depend from and therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 15 recites a dialysis connector comprising a valve element including "a flexible disk extending across the flow passage, the flexible disk including a plurality of movable elements formed on opposite sides of a first slit extending through the flexible disk, *the moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the flexible disk, the moveable elements are maintained in a closed position in which no flow is permitted past the flexible disk and, when a pressure at least as great as the threshold value is applied to the flexible disk, the moveable elements are moved to an open position separated from one another along the first slit permitting flow through the flow passage.*"

For the same reasons as described above in regard to claim 1, it is respectfully submitted that Paradis neither shows nor suggests "*moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the flexible disk, the moveable elements are maintained in a closed position in which no flow is permitted past the flexible disk,*" as recited in claim 15 and that claim 15 is allowable. Because claims 16, 17, and 23-25 depend from and therefore include all of the limitations of claim 15, it is respectfully submitted that these claim are allowable for the same reasons.

Claim 26 recites a flow shutoff device for medical applications comprising a pressure actuated valve mounted within a housing to selectively restrict flow therethrough, "the valve comprising a flexible disk including a plurality of movable elements separated by a slit extending through the disk, *the movable elements being biased toward a closed position and being movable to an open position when a pressure applied to the valve exceeds a predetermined threshold value*, wherein flow through the housing is prevented when the movable elements are in the closed position."

For the same reasons as described above in regard to claims 1 and 15, it is respectfully submitted that Paradis neither shows nor suggests a valve including movable elements "biased toward a closed position and being movable to an open position when a pressure applied to the valve exceeds a predetermined threshold value," as recited in claim 26 and that claim 26 is allowable.

Claims 6-7 and 9-11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Paradis

in view of Patent No. 5,810,789 to Powers et al. ("Powers"). The Examiner stated, in support of the rejection, that Paradis shows the valve substantially as claimed except for the housing attached to a dual lumen catheter with a valve apparatus in each lumen to regulate fluid flow but that Powers shows such a dual lumen arrangement. As stated above, Paradis neither shows nor suggests first movable members "biased so that, when a pressure less than a predetermined threshold value is applied to the first flexible disk, the first movable elements are maintained in a closed position in which no flow is permitted past the first flexible disk," as recited in claim 1, from which these claims depend. It is respectfully submitted that Powers fails to cure this deficiency.

Powers describes a dual lumen catheter 102 with a catheter body 122 comprising first and second lumens 118, 120. *Powers*, col. 8, ll. 38-43. Within the first lumen 118 is a two-way, three-position valve 168 biased toward a closed position in which fluid communication is precluded between first lumen 118 and an exterior surface 104 of the catheter 102. *Id.* at col. 11, ll. 1-5. The valve 168 is selectively operable from the closed position to either an inwardly or outwardly open position and permits flow in either direction. *Id.* at col. 11, ll. 5-8. Thus, it is respectfully submitted that the valve of Powers is incompatible with the check valve function of the valve of Paradis and that the check valve of Paradis is incompatible with the function of the valve 168 of Powers. It is therefore respectfully submitted that neither reference provides to one skilled in the art any motivation to make the combination suggested by the Examiner and that this combination is an impermissible hindsight reconstruction of the invention.

It is therefore respectfully submitted that claims 5-7 and 9-11 which depend from and therefore include all of the limitations of claim 1, are allowable over Paradis and Powers and withdrawal of this rejection is requested.

Claim 8, 18 and 19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Paradis in view of Patent No. 6,099,505 to Ryan et al. ("Ryan"). The Examiner stated, in support of the rejection, that Paradis shows the invention substantially as claimed except for a second pair of slits intersecting at the end of the first slit. The Examiner cites Ryan to cure this deficiency. However, it is respectfully submitted that Ryan does not cure the deficiencies pointed out in regard to the anticipation rejection of independent claim 1, from which claim 8 depends and in regard to the rejection of claim 15 from which claims 18 and 19 depend. That is, Ryan neither shows nor suggests first moveable members "biased so that, when a pressure less than a predetermined threshold value is applied to the first flexible disk, the first moveable elements are maintained in a closed position in which no flow is permitted past the first flexible disk," as

recited in claim 1. Nor does Ryan either show or suggest the similar recitations of claim 15 cited above in regard to the anticipation rejection.

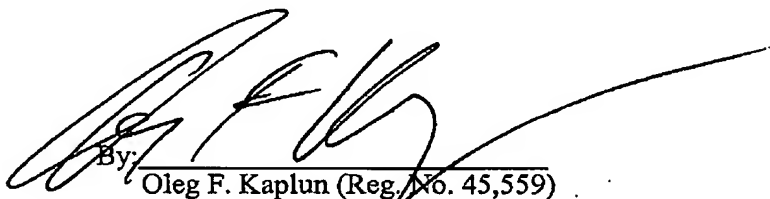
Furthermore, the valve assembly of Ryan is used specifically with a trocar such that the slits are opened only when a trocar is inserted therethrough. *See Ryan*, col. 7, ll. 14-20. Upon withdrawing the trocar 19 from the cannula 12 and valve assembly 16, the slit valve 162 closes automatically and prevents the escape of gas or fluids. *Id.* at col. 7, ll. 20-22. The opening and closing of the slit valve is never determined by the flow of fluid. Thus, it is respectfully submitted that neither reference provides motivation for the proposed combination and that this combination represents an impermissible hindsight reconstruction of the invention.

Because each of claims 8, 18 and 19 depends from and, therefore, includes all of the limitations of one of claims 1 and 15, it is respectfully submitted that these claims are not rendered obvious by Paradis in view of Ryan, and that this rejection should be withdrawn.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

Respectfully Submitted,

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